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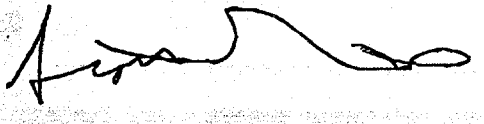
There can be no argument that if clinical tests were set up to prove whether or not a reprocessed used disposable device was safe for reuse, informed patient consent would be required. Strangely, proponents of reuse rely on a lack of any data to support a conclusion that reuse is safe and patients need not be told. Without sufficient data or approval from the FDA, the practice of reusing used disposable devices on patients is akin to human experimentation without patient consent.

I am thankful that the FDA is considering increased regulation of reprocessors, but, again, I do not believe the new policy is appropriate. The new policy would create new classifications of high, moderate and low risk devices. The existing regulations, however, already include a risk based classification scheme. The existing regulations also include regulations for reusable devices. Reprocessing a single use device simply renders it a reusable device. The new policy, therefore, is unnecessary.

The new policy is also insufficient to protect patient safety. Data proving safety and effectiveness will only be required for "high risk" devices, and FDA officials have stated publicly that very few devices will be deemed high risk. Reprocessors of low risk devices will receive even less regulatory oversight than they do today. As one example, many biopsy forceps are Class I exempt devices and will likely be deemed low risk devices, despite studies by manufacturers showing that many reprocessed biopsy forceps sitting on hospital shelves are contaminated with drug resistant bacteria. Importantly, biopsy forceps are critical devices which break the mucosal barrier when samples are taken and, thus, can easily pass bacteria remaining on the device to the unsuspecting patient. .

Reprocessors of single use devices claim to have the equipment and expertise necessary to "properly" reprocess used single use devices. They are, therefore, manufacturers in the eyes of healthcare workers and patients. In addition, reprocessing a single use device for reuse changes the device into a reusable device. Accordingly, reprocessors should be regulated in the same manner as original equipment manufacturers using the existing FDA regulations for reusable devices. To create a new regulatory policy wastes valuable FDA resources and delays regulatory enforcement putting, thus patients unnecessarily at risk for an undetermined period of time.

Sincerely,



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